Products:
E 01 2200 Localizer Headband
E 01 2202 Localizer Adhesive Pad
E 01 2202 C Localzer Adhesive Pad C-Type

Manufacturer:
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CE

For US market only. This document is intended to provide information to an audience of the US.

Explanation of symbols

	Manufacturer / Manufacturing date
REF	Reference number/Order number
LOT	Production lot /batch
	To ensure safety, follow the instructions for use
	Consult instructions for use. Follow the supporting documentation
35°C 15°C	Recommended storage temperature +15°C to +35°C
75% % 30%	Recommended storage humidity 30% to 75% without condensation
1060 hPa 700 hPa	Recommended storage air pressure 700 hPa to 1060 hPa
	Applied part type BF
	This is the general warning sign. It is used to alert the user to potential hazards. All safety messages that follow this sign shall be obeyed to avoid possible harm
NON STERILE	The device is delivered non-sterile
Rx	Federal law (USA) restricts this device to sale by or on order of a physician.

1. General information

The products Localizer Headband, Localizer Adhesive Pad and Localizer Adhesive Pad C-Type are product variants of a patient reference localisators for image guided surgical procedures and are referred to as ‚*localizers*' below.

The localizers are accessories to the Fiagon navigation system produced by Fiagon GmbH.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION: Read the instructions for use carefully before using the instrument

CAUTION: Before using it, the instrument must be reprocessed according to the reprocessing instructions. The localizers Localizer Headband, Localizer Adhesive Pad and Localizer Adhesive Pad C-Type are not sterilizable. They need to be covered sterile during the operation.

2. Indications for Use / Field of application

The application of the localizers is limited to the indications for use described here.

The localizers are designed to be used with the fiagon navigation system for the ENT and ENT related scull base procedures supported by the system.

Refer to the instructions for use and the fiagon application notes of the procedures for guidance on selection of a suitable localizer type for each procedure.

The navigation system and its accessories are intended for use by healthcare professionals only. In addition, the users receive a training. The operator, i.e., the person or facility that is responsible for the use and service of the system, must ensure that all users of the system receive an adequate introduction into the system in accordance with valid laws and regulations. An operator is everyone who uses the system.

The localizer as a part of the navigation system serves as a reference fixed to the patient. The instructions for use of the navigation system describe the proper use of the entire system in detail.

The localizer may only be used if the safety instructions of the navigation system and other connected devices have been followed.

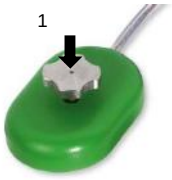
Contraindications

Localizer Headband should not be used in procedures where a non sterile headband round the patients head cannot be applied for reasons of sterile covering (such as procedure at the lateral scull base and cranial procedures).

CAUTION: The localizer should not be re-processes and reused after it has been used with patients with suspected Creutzfeld-Jakob disease. There is a risk of disease transmission, dispose the instrument in after the operation.

MR UNSAVE: The instrument must not be exposed to MRI or used in a Magnetic Resonance Environment. The MRI exposure might magnetize the sensor. This might lead to a misleading navigation information

3. Localizer Headband (E 01 2200) – Description of use



1. Pit for rejecting registration

Localizer headband is fixed with the single use component E 00 3000 headband

Placing and Fixing the patient localizer headband

1. Clean the forehead of the patient with a non-greasing disinfection lotion
2. Take a new headband out of its package unfold it and open one side of the headband straps
3. Remove the protective sheet from the pad on the back of the headband.
4. Place the white plastic part with the pad facing the patient onto the forehead and press it down gently.
5. Place the headband around the head of the patient and pull it tight and close the straps.
6. Place the patient localizer onto the headband and fasten it with the screw.

CAUTION: Make sure the headband is positioned tightly to keep it from slipping during treatment. Gently move the patient localizer back and forth to check if the headband is positioned tight enough.

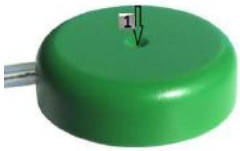
CAUTION: The headband may produce pressure marks on the patient's forehead during longer operations.

Covering patient and localizer

Use sterile drapes to cover the patient. The cable of the localizer must not be too tight. We recommend to use self-adhesive film to cover the localizer, thereby leaving the calibration pit clear.
- 3M Steri-Drape 2, Art. 2037
- OPRAFLEX Inzisionsfolie (incision film) 30 x 27 cm

CAUTION: Make sure that the selected registration markers are not covered with sterile drapes. The facial area of the patient above the upper jaw must not be covered.

4. Localizer Adhesive Pad / Localizer Adhesive Pad C-Type (E 01 2202/ E 01 2202 C) – Description of use



1 Pit for rejecting registration

Localizer adhesive pad is fixed with the single use component E 01 3001 Adhesive pad.

Placing and Fixing the patient localizer

- **Localizer Adhesive Pad / Localizer Adhesive Pad C-Type**

1. Clean the forehead of the patient with a non-greasing disinfection lotion
2. Take a new adhesive from the backing film.
3. Stick it to the bottom side of the localizer
4. Remove the protective sheet from the pad labeled "Patient Side"
5. Place the patient localizer with the pad facing the patient onto the forehead and press it down gently.

CAUTION: Make sure the localizer is fix. Gently move the patient localizer back and forth to check if the localizer sticks in intended position during operation.

Covering patient and localizer

Use sterile drapes to cover the patient. The cable of the localizer must not be too tight. We recommend to use self-adhesive film to cover the localizer, thereby leaving the calibration pit clear.
- 3M Steri-Drape 2, Art. 2037
- OPRAFLEX Inzisionsfolie (incision film) 30 x 27 cm

CAUTION: Make sure that the selected registration markers are not covered with sterile drapes. The facial area of the patient above the upper jaw must not be covered.

5. Preparation for the navigation

Connect the plug of the localizer with the navigation module. (black socket for “localizer” for für E 01 2200 Localizer Headband and E 01 2202 Localizer Adhesive Pad and green socket for E 01 2202 C Localizer Adhesive Pad C-Type). Note that the white marking at the plug is at 12 o'clock position.

Once the localizer is connected, you will hear a confirmation tone.

NOTE: Before using the navigation the patient registration has to be done according to the desciption of the application. Consult the instructions for use of the resp. navigation application for guidance.

NOTE: If the localizer does not register at the navigation system, it cannot be used for the navigation**.**

NOTE: For connecting the localizer to the navigation unit via a longer distance use the extension cable („Extension Cable Localizer“ for Localizer Headband and Localizer Adhesive Pad and „Extension Cable Instrument“ for Localizer Adhesive Pad C-Type, accessories to the navigation unit).

6. After the operation

After the operation disconnect the localizer from the navigation unit. Do this by pulling the plug directly. Do not pull the cable or the bend relieve. This might damage the cable.

Localizer Headband: Unscrew the localizer and remove it from the headband. Unstrap the headband and dispose it. Re-process the localizer according to the reprocessing instructions on pages 7.

Localizer Adhesive Pad/ Localizer Adhesive Pad C-Type: Remove the localizer from the skin. Remove the pad from the localizer and dispose the pad. Re-process the localizer according to the reprocessing instructions on pages 7.

CAUTION: The localizer should not be re-processes and reused after it has been used with patients with suspected Creutzfeld-Jakob disease. There is a risk of transmission. Dispose the instrument in this case after the operation.

7. Specifications

Type	E 01 2200 Localizer Headband	E 01 2202 Localizer Adhesive Pad E 01 2202 C Localizer Adhesive Pad C-Type
Use with fixation material	E 00 3000 Headband	E 01 3001 Adhesive Pad
Operating conditions	Temperature: +15°C to + 35°C, Humidity: 30% to 75% without condensation Air pressure: 1060 hPa to 700 hPa	
Transport conditions	Temperature: -10°C to + 40°C, Humidity: 30% to 75% without condensation Air pressure: 1060 hPa to 700 hPa	
Storage conditions	Protected against dust, moisture and recontamination. Recommended storage temperature: +15° to +35°C	

To ensure that the instrument is intact, pay attention to the notes regarding the transport and storage conditions as well as the notes regarding the application of the instrument!

8. Reprocessing instructions

The localizers are reusable components.

WARNING: The patient localizer must not be sterilized

Detailed instructions for reprocessing the localizers without patient and tissue contact:	
Disassembling	**With exception of the screw, the instruments are reprocessed as a complete unit with cable and connector. Cable or connector must not be disassembled.** **Localizer Headband:** Remove the screw from the case and separately treat both parts using the following steps: **Localizer Adhesive Pad/ Localizer Adhesive Pad C-Type:** No dissembling. Reprocess the complete component using the following steps:
Cleaning and disinfection	Materials: - CaviWipes™ (intermediate-level disinfectant towelettes, aldehydes free) or equivalent disinfectant towelettes Method: 1. Clean exterior surfaces of case, cable, screw, and outer face of connector,with a first towelette to remove debris and bioburden, discard used towelette. 2. Disinfect surface of all above mentioned parts with a second new/unused towelette. Leave surface wet for three (3) minutes, discard used towelette. **Do not immerse the localizer in a disinfectant or cleaning agent.** **Do not rinse the localizer**.
Cleaning inspection	Examine surfaces for visible soil/detergent/debris. If residual soil or debris are still visible on the instrument after reprocessing, all cleaning and disinfection steps should be repeated.
Inspection	The instrument should be inspected after cleaning and before use for surgery. Visually inspect the instrument for damage or wear. Visually inspect the cable and connectors.
Reassemby	**Localizer Headband:** Upon cleaning and inspection, insert the screw back into the localizer headband case, and turn until the thread passes the case completely. **Localizer Adhesive Pad/ Localizer Adhesive Pad C-Type**: no assembly necessary
Point of Use / Protective Wraps:	After cleaning and disinfection, place the localizer with the mounted registration screw into protective wrapping (Pouches: Steriking (Healthmark Ind Co.)Size 7” x 12.5” Pouch item no.: .#33 or equivalent pouch). Pouch is not to be sealed, just folded